



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

**GENERIC DATA CALL-IN NOTICE**

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient(s) identified in Attachments 2 and 3 of this Notice to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary for the Registration Review of your pesticide product(s) in its Registration Review case and to maintain the continued registration of your product(s) containing the active ingredient(s). Within 90 days after you receive this Notice, you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 5; or,
2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form, (see section III-B); or,
3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, *Generic Data Call-In Response Forms And Instructions* Form, as well as a list of all registrants who were sent this Notice (Attachment 4).

You may respond to this Generic Data Call-In Notice either electronically through the Central Data Exchange (CDX) or by mail as described in Attachment 1. When submission of responses is discussed throughout this Notice, either method can be used.

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended; sections 3(g)(2)(A) and (B) of FIFRA, as amended; and/or section 408(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FFDCA). This notice is issued as part of Registration Review and is also authorized by 40 CFR Part 155.40, et seq., which is the Agency's Registration Review regulations. Collection of this information is in compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) as approved by the Office of Management and Budget (OMB) under Control Number 2070-0174.

This Notice is divided into six sections and five Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

- Section I. Why You Are Receiving This Notice
- Section II. Data Required By This Notice
- Section III. Compliance With Requirements Of This Notice
- Section IV. Consequences Of Failure To Comply With This Notice
- Section V. Registrants' Obligation To Report Possible Unreasonable Adverse Effects
- Section VI. Inquiries And Responses To This Notice

The Attachments to this Notice are:

- Attachment 1. Data Call-In Chemical Status Sheet
- Attachment 2. Generic Data Call-In Response Forms and Instructions
- Attachment 3. Generic Requirements Status and Registrant's Response Forms and Instructions
- Attachment 4. List of All Registrants Sent this Data Call-In Notice
- Attachment 5. Additional Documents and Information
  - Confidential Statement of Formula and Instructions
  - Certification of Attempt to Enter into an Agreement with Registrants for Development of Data
  - Certification with Respect to Citation of Data
  - Paperwork Reduction Act Notification for DCI Respondents

## **SECTION I. WHY YOU ARE RECEIVING THIS NOTICE**

The Agency has reviewed existing data for the active ingredient(s) identified in Attachments 2 and 3 of this Notice, and reevaluated the data needed to support continued registration of products containing the subject active ingredient(s) and the continuation of any existing tolerances or exemptions for such active ingredient. This reevaluation conducted as part of Registration Review identified additional data necessary to assess the health and safety of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredient(s).

## **SECTION II. DATA REQUIRED BY THIS NOTICE**

### **A. DATA REQUIRED**

The data required by this Notice are specified in the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form. Depending on the results of the studies required in this Notice, additional testing may be required.

### **B. SCHEDULE FOR SUBMISSION OF DATA**

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form, within the time frames provided.

### **C. TESTING PROTOCOL**

All studies required under this Notice must be conducted in accordance with protocols which meet the purpose of the test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established and which provide data of suitable quality and completeness as typified by the protocols cited in the guidelines.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-605-6000) and on the EPA's Chemical Safety and Pollution Prevention website (<http://www.epa.gov/test-guidelines-pesticides-and-toxic-substances>).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR Part 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from 2001 L Street, N.W., Suite 650, Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350) and electronically on the OECD website ([http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals\\_chem\\_guide\\_pkg-en](http://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals_chem_guide_pkg-en)).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices (40 CFR Part 160).

**D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) OR 4 DATA CALL-IN NOTICES ISSUED BY THE AGENCY**

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

**SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE**

**A. SCHEDULE FOR RESPONDING TO THE AGENCY**

The appropriate responses initially required by this Notice must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

**B. OPTIONS FOR RESPONDING TO THE AGENCY**

The options for responding to this Notice are: 1) voluntary cancellation, 2) delete use(s), (3) claim generic data exemption, (4) agree to satisfy the data requirements imposed by this Notice or (5) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one

or both must be used in your response to the Agency. These forms are the Attachment 2, *Generic Data Call-In Response Forms And Instructions* Form and the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form. The Attachment 2, *Generic Data Call-In Response Forms And Instructions* Form must be submitted as part of every response to this Notice. Note that the company's authorized representative is required to sign the first page of the Attachment 2, *Generic Data Call-In Response Forms And Instructions* Form and the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, write or email EPA as indicated in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient(s) that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Attachment 2, *Generic Data Call-In Response Forms And Instructions* Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Attachment 2, *Generic Data Call-In Response Forms And Instructions* Form. If you choose this option, this is the only form that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Use Deletion - You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form, a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 on the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form. You must also complete an Attachment 2, *Generic Data Call-In Response Forms And Instructions* Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Division (Main Office), (703) 305-5447.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, must bear an amended label.

3. Generic Data Exemption - Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient(s) if the active ingredient(s) in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient(s). EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:
  - a. The active ingredient(s) in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient(s) and is purchased from a source not connected with you; and,
  - b. Every registrant who is the ultimate source of the active ingredient(s) in your product subject to this DCI must be in compliance with the requirements of this

Notice and must remain in compliance; and

- c. You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Attachment 2, *Generic Data Call-In Response Forms And Instructions* Form and all supporting documentation. The Generic Data Exemption is item number 6a on the Attachment 2, *Generic Data Call-In Response Forms And Instructions* Form. If you claim a generic data exemption, you are not required to complete the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form. Generic Data Exemption cannot be selected as an option for product specific data.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

4. Satisfying the Data Requirements of this Notice - There are various options available to satisfy the data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form and option 6b and 7 on the Attachment 2, *Generic Data Call-In Response Forms And Instructions* Form. If you choose option 6b or 7, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.
5. Request for Data Waivers - Data waivers are discussed in Section III-D of this Notice and are covered by options 8 and 9 on the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

#### C. SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Attachment 2 *Generic Data Call-In Response Forms And Instructions* Form that you agree to satisfy the data requirements (i.e. you select option 6b and/or 7), then you must select one of the six options on the Attachment 2, *Generic Data Call-In Response Forms And Instructions* Form related to data production for each data requirement. Your option selection is to be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

1. I will generate and submit data within the specified time frame (Developing Data),
2. I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing),

3. I have made offers to cost-share (Offers to Cost Share),
4. I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study),
5. I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study),
6. I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study).

Option 1, Developing Data –

If you choose to develop the required data, then it must be in conformance with the Agency's deadlines and other requirements that are referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted in accordance with the Pesticide Assessment Guidelines (PAG), be in conformance with Pesticide Registration Notice (PRN) 2011-3 entitled "Standard Format for Data Submitted Under FIFRA and Certain Provisions of FFDCA" (<http://www.epa.gov/pesticide-registration/pesticide-registration-notice-year>), and, as applicable, comply with 40 CFR Part 26, "Protection of Human Subjects." In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol, you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost-share or agreeing to share in the cost of developing that study. A 90-day progress report must be submitted for all studies. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratories or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the *Generic Requirements Status and Registrant's Response Forms and Instructions* Form (Attachment 3) are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted

by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s) and the affected tolerances or exemptions are subject to revocation.

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirement(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, then the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

#### Option 2, Agreement to Share in Cost to Develop Data –

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. FIFRA section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

#### Option 3, Offer to Share in the Cost of Data Development –

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, *Certification of Offer to Cost Share in the Development of Data* (see Attachment 5). In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a *Generic Data Call-In Response*

*Forms And Instructions Form (Attachment 2) and a Generic Requirements Status and Registrant's Response Forms and Instructions Form (Attachment 3) committing to develop and submit the data required by this Notice.*

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

#### Option 4, Submitting an Existing Study –

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the existing study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following four criteria must be clearly met:

- a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR Part 160.3(7) "*raw data* means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. *Raw data* may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR Part 160.3(7), means "any material derived from a test system for examination or analysis."
- b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.



- c. You must certify that each study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR Part 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. You must identify each deviation from the PAG and you need to explain and justify why the study should be accepted notwithstanding such deviation(s). It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.
- d. If any existing study involves testing subject to 40 CFR Part 26, you must comply with all applicable requirements in EPA's regulations at 40 CFR Part 26 entitled "Protection of Human Subjects."

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such a study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as per PRN 2011-3.

#### Option 5. Upgrading a Study –

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, write or email EPA as indicated in Attachment 1. If you submit data to upgrade an existing study, you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and be in conformance with PRN 2011-3.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

#### Option 6, Citing Existing Studies –

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of Certification with Respect to Citations of Data (in PRN 2011-3) EPA Form 8570-34.

#### D. REQUESTS FOR DATA WAIVERS

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are inapplicable and do not apply to your product.

1. Low Volume/Minor Use Waiver (Option 8 on the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form) Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision EPA considers as low volume pesticides only those active ingredient(s) whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient(s) is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient(s) are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An exemption will not be granted if any registrant of the active ingredient(s) elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following

information, as applicable to your product(s), as part of your 90-day response to this Notice:

- a. Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient(s). If applicable to the active ingredient(s), include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.
- b. Provide an estimate of the sales (pounds and dollars) of the active ingredient(s) for each major use site. Present the above information by year for each of the past five years.
- c. Total direct production cost of product(s) containing the active ingredient(s) by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.
- d. Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient(s) by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient(s), such as costs of initial registration and any data development.
- e. A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.
- f. A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.
- g. For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient(s), direct production costs of product(s) containing the active ingredient(s) (following the parameters in item c above), indirect production costs of product(s) containing the active ingredient(s) (following the parameters in item d above), and costs of data development pertaining to the active ingredient(s).
- h. A description of the importance and unique benefits of the active ingredient(s) to users. Discuss the use patterns and the effectiveness of the active ingredient(s) relative to registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient(s), providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient(s) in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s):
  - (a) documentation of the usefulness of the active ingredient(s) in Integrated Pest Management,

- (b) description of the beneficial impacts on the environment of use of the active ingredient(s), as opposed to its registered alternatives,
- (c) information on the breakdown of the active ingredient(s) after use and on its persistence in the environment, and
- (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume minor use waiver will result in denial of the request for a waiver. Low volume minor use waivers may not be available for data required for continuation of tolerances or exemptions.

2. Request for Waiver of Data (Option 9 on the Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form). This option may be used if you believe that a particular data requirement should not apply because the corresponding use is no longer registered and no tolerance or tolerance exemption exists or the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You must also submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice do not apply to your product(s), you will not be required to supply the data pursuant to FIFRA section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form indicating the option chosen.

#### **SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE**

##### **A. NOTICE OF INTENT TO SUSPEND REGISTRATION/ORDER REVOKING OR MODIFYING TOLERANCE OR EXEMPTION**

The Agency may issue a Notice of Intent to Suspend products subject to this Notice or an order revoking or modifying associated tolerances or tolerance exemptions due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B) or FFDCA section 408(f). Events which may be the basis for issuance of a Notice of Intent to Suspend or of an order revoking or modifying associated tolerances or exemptions include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.
2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.
3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.
4. Failure to submit on the required schedule acceptable data as required by this Notice.
5. Failure to take a required action or submit adequate information pertaining to any option

chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.
7. Withdrawal of an offer to share in the cost of developing required data.
8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer, or failure of a registrant on whom you rely for a generic data exemption either to:
  - a. Inform EPA of intent to develop and submit the data required by this Notice on an Attachment 2, *Generic Data Call-In Response Forms And Instructions* Form and an Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form; or,
  - b. Fulfill the commitment to develop and submit the data as required by this Notice; or,
  - c. Otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.
9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

**B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE**

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend or an order revoking or modifying a tolerance or tolerance exemption. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.
2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.
3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice and that set forth in PRN 2011-3. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.
4. Requirements, as applicable, set forth in 40 CFR Part 26 entitled "Protection of Human

Subjects.”

C. EXISTING STOCKS OF SUSPENDED OR CANCELED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or canceled if doing so would be consistent with the purposes of FIFRA.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a FIFRA section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily canceled products containing an active ingredient(s) for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell distribute or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

**SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS**

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies

regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

## **SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE**

If you have any questions regarding the requirements and procedures established by this Notice, contact EPA as listed in Attachment 1, the *Data Call-In Chemical Status Sheet*.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Attachment 2, *Generic Data Call-In Response Forms And Instructions* Form and a completed Attachment 3, *Generic Requirements Status and Registrant's Response Forms and Instructions* Form and any other documents required by this Notice, and must be submitted either electronically through CDX or by mail as identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Attachment 2, *Generic Data Call-In Response Forms And Instructions* Form need be submitted.

Sincerely,

A handwritten signature in black ink, appearing to read 'Yu-Ting Guilaran', with a long horizontal line extending to the right.

Yu-Ting Guilaran  
Director  
Pesticide Re-evaluation Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency

## **Attachment 1. Data Call-In Data Chemical Status Sheet**



## DATA CALL-IN CHEMICAL STATUS SHEET

Submit all responses to the GDCI using the information below. To expedite processing, include the GDCI identification number (e.g., GDCI-555555-5555) in the Subject line of all DCI-related correspondence.

## INQUIRIES AND RESPONSES TO THIS NOTICE

All responses to this notice for the GDCI data requirements are to be submitted electronically through the Central Data Exchange (CDX) or by mail as described below.

### **If You Choose to Respond through the Central Data Exchange (CDX):**

The DCI receipt acknowledgement, 90-day response, and data can be submitted through CDX via the DCI application of the Pesticide Submission Portal (PSP). If you have a CDX account with access to the PSP, you may follow the link below to sign in, acknowledge receipt, and access your DCI(s): <https://cdx.epa.gov/>.

A user guide is available for instructions on what to do if you do not have a CDX account (page 16 in the link below) or if you need to add PSP to your account (page 55 in the link below): [https://cdx.epa.gov/content/documents/PSP/OPP\\_CDX\\_Pesticide\\_Submission\\_PortalRegistration\\_UserGuidev1.0p.pdf](https://cdx.epa.gov/content/documents/PSP/OPP_CDX_Pesticide_Submission_PortalRegistration_UserGuidev1.0p.pdf).

### **If You Choose to Respond by Mail:\***

#### By US mail:

Document Processing Desk (DCI/PRD)  
Attn:  
US EPA (7508P)  
1200 Pennsylvania Ave. N.W.  
Washington, DC 20460  
Arlington, VA 22202

#### By express or courier service:

Document Processing Desk (DCI/PRD)  
Attn:  
US EPA (7508P)  
One Potomac Yard (South Building)  
2777 S. Crystal Dr.

\*NOTE: If this DCI was sent to you via email, you may acknowledge receipt via email.

## **Attachment 2. Generic Data Call-In Response Form and Instructions**

United States Environmental Protection Agency  
Washington, D.C. 20460  
**DATA CALL-IN RESPONSE**

OMB Approval 2070-0174  
EPA FORM 6300-4

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.  
Use additional sheet(s) if necessary.

## 1. Company Name and Address

BAYER CROPSCIENCE LP  
2 T.W. ALEXANDER DRIVE, P.O. Box 12014  
RESEARCH TRIANGLE PARK, NC 27709

## 2. Case # and Name

N/A - Tebuconazole  
Chemical # and Name: 128997  
Tebuconazole

## 3. Date and Type of DCI and Number

14-Sep-2017  
GENERIC  
ID # GDCL-128997-1598

## 4. EPA Product Registration

5. I wish to cancel  
this product  
registration  
voluntarily

## 6. Generic Data

6a. I am claiming a Generic Data  
Exemption because I obtain the  
active ingredient from the source  
EPA registration number listed  
below.

6b. I agree to satisfy Generic Data  
Requirements as indicated on the  
attached form entitled  
"Requirements Status and  
Registrant's Response."

## 7. Product Specific Data

7a. My product is an MUP and I  
agree to satisfy the MUP  
requirement on the attached form  
entitled "Requirements Status and  
Registrant's Response."

7b. My product is an EUP and I  
agree to satisfy the EUP  
requirement on the attached form  
entitled "Requirements Status and  
Registrant's Response."

264-748

N/A

N/A

8. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative \_\_\_\_\_

9. Date

10. Name of Company

11. Phone Number

## INSTRUCTIONS: DATA CALL-IN RESPONSE FORM

These instructions apply to the form titled "Data Call-In Response" and are to be used to respond to generic Data Call-Ins issued as part of EPA's Registration Review Program under the Federal Insecticide, Fungicide, and Rodenticide Act. Read these instructions carefully before filling out the forms.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. N.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

Item #	GENERIC DATA CALL-IN RESPONSE Information
Item 1.	This item identifies your company name, number and address.
Item 2.	This item identifies the case number, case name, EPA chemical number and chemical name.
Item 3.	This item identifies the type of Data Call-In. The date of issuance is date stamped.
Item 4.	This item identifies the EPA product registrations relevant to the data all-in. Note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.
Item 5.	Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-in requires both generic and product specific data, you must complete item 5 on both Data Call-In response form. You do not need to complete any item on the Generic Requirements Status and Registrant's Response Forms and Instructions Form.

Item #	DATA CALL-IN RESPONSE Information
Item 6a.	<p>Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice. If you are eligible for or claim a Generic Data Exemption, enter the EPA Registration Number of each registered source of that active ingredient that you use in your product.</p> <p>Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or Use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item</p>
Item 6b.	<p>Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the "Generic Requirements Status and Registrant's Response Forms and Instructions" Form that indicates how you will satisfy those requirements.</p> <p>Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, supply all relevant details so that EPA can ensure that its records are correct.</p>
Item 7a.	Not Applicable
Item 7b.	Not Applicable
Item 8.	This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialed and dated in the space provided for the certification.
Items 9, 10, 11.	Provide date of signature, name of company, and telephone number.

## **Attachment 3. Generic Requirements Status and Registrant's Response Form and Instructions**

United States Environmental Protection Agency  
Washington, D.C. 20460  
**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

OMB Approval 2070-0174  
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address  BAYER CROPSCIENCE LP 2 T.W. ALEXANDER DRIVE, P.O. Box 12014 RESEARCH TRIANGLE PARK, NC 27709		2. Case # and Name  N/A - Tebuconazole Chemical # and Name: 128997 Tebuconazole				3. Date and Type of DCI and Number  14-Sep-2017 GENERIC ID # GDCI-128997-1598			
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	<b>Applicator Exposure Data Requirements (Conventional Chemical)</b>								
875.1200	Dermal exposure--Indoor (15, 19, 41)	Y				A,C,Q,X,BB	TEP	12	
875.1400	Inhalation exposure--indoor (15, 19, 41)	Y				A,C,Q,X,BB	TEP	12	
875.1700	Product Use Information (15, 22)	N				A,C,Q,X,BB	TEP	12	
	<b>Nontarget Plant Protection Data Requirements (Conventional Chemical)</b>								
850.4100	Seedling Emergence and Seedling Growth (6, 14)	N				A,C,Q,X,BB	TEP	12	
850.4150	Vegetative Vigor (7, 14)	N				A,C,Q,X,BB	TEP	12	
	<b>Post-Application Exposure Data Requirements (Conventional Chemical)</b>								
875.2100	Foliar dislodgeable residue dissipation (14, 28)	N				A,C,Q,X,BB	TEP	12	
875.2300	Indoor surface residue dissipation (15, 17, 39, 41)	Y				A,C,Q,X,BB	TEP	12	
10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.  Signature and Title of Company's Authorized Representative _____							11. Date		
12. Name of Company							13. Phone Number		

United States Environmental Protection Agency  
Washington, D.C. 20460  
**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

OMB Approval 2070-0174  
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

<b>1. Company Name and Address</b>  BAYER CROPSCIENCE LP 2 T.W. ALEXANDER DRIVE, P.O. Box 12014 RESEARCH TRIANGLE PARK, NC 27709	<b>2. Case # and Name</b>  N/A - Tebuconazole Chemical # and Name: 128997 Tebuconazole	<b>3. Date and Type of DCI and Number</b>  14-Sep-2017 GENERIC ID # GDCI-128997-1598							
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
	<b>Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)</b>								
850.2100	Avian acute oral toxicity test (14, 23)	N				A,C,Q,X,BB	TGAI	12	
850.3020	Honey bee acute contact toxicity (8, 14, 21)	N				A,C,Q,X,BB	TGAI	12	
850.3030	Honey bee toxicity of residues on foliage (2, 9, 14, 41)	Y				A,C,Q,X,BB	TEP	12	
850.3040	Field testing for pollinators (1, 3, 14, 20, 41)	Y				A,C,Q,X,BB	TEP	24	
835.1110	Activated sludge sorption isotherm (15, 34)	N				A,C,Q,X,BB	TGAI	12	
835.3110	Ready biodegradability (15, 33)	N				A,C,Q,X,BB	TGAI	12	
835.3220	Porous pot test (15, 32)	N				A,C,Q,X,BB	TGAI	12	
835.3240	Simulation Test-Aerobic Sewage Treatment-Activated Sludge (15, 31)	N				A,C,Q,X,BB	TGAI	12	



United States Environmental Protection Agency  
Washington, D.C. 20460  
**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

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EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address  BAYER CROPSCIENCE LP 2 T.W. ALEXANDER DRIVE, P.O. Box 12014 RESEARCH TRIANGLE PARK, NC 27709		2. Case # and Name  N/A - Tebuconazole Chemical # and Name: 128997 Tebuconazole				3. Date and Type of DCI and Number  14-Sep-2017 GENERIC ID # GDCI-128997-1598			
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
835.3280	Simulation Tests to Assess the Biodegradability of Chemicals (15, 30)	N				A,C,Q,X,BB	TGAI	12	
850.3300	Modified Activated Sludge, Respiration Inhibition Test (15, 18, 24, 29)	N				A,C,Q,X,BB	TGAI	12	
850.4500	Algal Toxicity (16, 25, 38)	N				A,C,Q,X,BB	TGAI, TEP	12	
850.4550	Cyanobacteria (Anabaena flos-aquae) Toxicity (16, 25)	N				A,C,Q,X,BB	TGAI, TEP	12	
850.6100	Environmental Chemistry Methods and Associated Independent Laboratory Validation (14, 35)	N				A,C,Q,X,BB	TGAI	12	
SS-1196	Whole Sediment: Chronic toxicity to saltwater invertebrates (16, 37, 41)	Y				A,C,Q,X,BB	TGAI	24	
SS-1197	Whole Sediment: Chronic toxicity to freshwater invertebrates (16, 36, 41)	Y				A,C,Q,X,BB	TGAI	24	
SS-1311	Honey bee adult acute oral toxicity (10, 14)	N				A,C,Q,X,BB	TGAI	12	
SS-1312	Honey bee larvae acute oral toxicity (13, 14)	N				A,C,Q,X,BB	TGAI	12	

United States Environmental Protection Agency  
Washington, D.C. 20460  
**REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE**

OMB Approval 2070-0174  
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

<b>1. Company Name and Address</b>  BAYER CROPSCIENCE LP 2 T.W. ALEXANDER DRIVE, P.O. Box 12014 RESEARCH TRIANGLE PARK, NC 27709	<b>2. Case # and Name</b>  N/A - Tebuconazole Chemical # and Name: 128997 Tebuconazole	<b>3. Date and Type of DCI and Number</b>  14-Sep-2017 GENERIC ID # GDCI-128997-1598							
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
SS-1313	Honey bee adult chronic oral toxicity (11, 14, 41)	Y				A,C,Q,X,BB	TGAI	12	
SS-1314	Honey bee larvae chronic oral toxicity (12, 14, 41)	Y				A,C,Q,X,BB	TGAI	12	
SS-1315	Semi-field testing for pollinators (5, 14, 26, 27, 41)	Y				A,C,Q,X,BB	TGAI, TEP	24	
SS-1316	Field trial of residues in pollen and nectar (4, 14, 40)	Y				A,C,Q,X,BB	TEP	24	

United States Environmental Protection Agency  
Washington, D.C. 20460

**FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS**

Case # and Name: N/A - Tebuconazole  
DCI Number: GDCI-128997-1598

**Key:** [Degr] = Degradate; [d-EP] = diluted End-use product; [EP] = End-use product; [MET] = Plant metabolite; [MP] = Manufacturing-use product; [PAI] = Pure Active Ingredient; [PAIRA] = Pure active ingredient radio-labelled; [RAMET] = Radio-labeled plant metabolite; [ROC] = Residue of Concern; [TEP] = Typical end-use product; [TGAI] = Technical grade of the active ingredient; [TW] = Treated wood

**Use Categories Key:**

A - Terrestrial food crop  
  
C - Terrestrial nonfood crop  
  
Q - Residential outdoor use  
  
X - Materials preservatives  
  
BB - Wood preservatives

**Footnotes:** The following footnotes are referenced in column two (5. Study Title) of the Requirements Status and Registrant's Response form. These footnotes apply in addition to any test notes included in 40 CFR Part 158 with respect to the particular data requirement.

- 1 USEPA. 2012c. "Field Testing for Pollinators." Ecological Effects Test Guidelines OCSPP 850.3040. EPA 712-C-017.
- 2 USEPA. 2012b. "Honey Bee Toxicity of Residues on Foliage." Ecological Effects Test Guidelines OCSPP 850.3030. EPA 712-C-018.
- 3 Tier 3 study. The need for a field test for pollinators will be determined based on the results of lower-tiered tests and/or other lines of data and the need for a refined pollinator risk assessment.
- 4 Tier 2 study. The need for this study will be determined based on the results of lower-tiered studies and/or other lines of data and the need for a refined pollinator risk assessment.
- 5 Tier 2 study. The need for a semi-field test for pollinators (i.e., either a field-feeding test or a tunnel test) will be determined based on the results of lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment.
- 6 Tier 2 data on monocots are required.
- 7 Tier 2 data on dicots and monocots are required.
- 8 Tier 1 study. USEPA. 2012a. "Honey Bee Acute Contact Toxicity" Ecological Effects Test Guidelines OCSPP 850.3020. EPA 712-C-019
- 9 Tier 1 study. Guideline 850.3030 data are required when the product formulation contains one or more active ingredient(s) having an acute LD50 of < 11 micrograms per bee as determined in the honey bee acute contact study and the use pattern(s) indicate(s) that honey bees may be exposed to the pesticide.
- 10 Tier 1 study. See the OECD 213: OECD Guidelines for the Testing of Chemicals. Honeybees, Acute Oral Toxicity Test. 213. [http://www.oecd-ilibrary.org/environment/test-no-213-honeybees-acute-oral-toxicity-test\\_9789264070165-en](http://www.oecd-ilibrary.org/environment/test-no-213-honeybees-acute-oral-toxicity-test_9789264070165-en)
- 11 Tier 1 study. OECD has not yet finalized test guidelines for chronic studies, and efforts are underway to develop standardized guidelines for assessing the effects from chronic exposure to adult and larvae in the laboratory. Discussion of the study design elements for the 10-day adult toxicity test can be found in Appendix O of the European Food Safety Authority (EFSA) guidance document: EFSA. 2013. Guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees). EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295. Available online at: <https://www.efsa.europa.eu/en/efsajournal/pub/3295>
- 12 Tier 1 study. OECD has not yet finalized test guidelines for chronic studies with honey bee larvae. OECD Draft Guidance Document Honey Bee (Apis mellifera) Larval Toxicity Test, Repeated Exposure. [https://www.oecd.org/env/ehs/testing/Honeybee%20larval%20rep%20expo\\_REV%20following%20April%202015%20expert%20meeting\\_Draft%2020%20July%202015.pdf](https://www.oecd.org/env/ehs/testing/Honeybee%20larval%20rep%20expo_REV%20following%20April%202015%20expert%20meeting_Draft%2020%20July%202015.pdf)
- 13 Tier 1 study. OECD Test Guideline 237 may be used to develop a protocol for this study (OECD. 2013 Guidelines for Testing Chemicals. Honey bee (Apis mellifera) larval toxicity test, single exposure.) See: [http://www.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure\\_9789264203723-en](http://www.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure_9789264203723-en)
- 14 This study is required only in support of conventional uses.

United States Environmental Protection Agency  
Washington, D.C. 20460

## FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: N/A - Tebuconazole

DCI Number: GDCI-128997-1598

**Key: [Degr] = Degradate; [d-EP] = diluted End-use product; [EP] = End-use product; [MET] = Plant metabolite; [MP] = Manufacturing-use product; [PAI] = Pure Active Ingredient; [PAIRA] = Pure active ingredient radio-labelled; [RAMET] = Radio-labeled plant metabolite; [ROC] = Residue of Concern; [TEP] = Typical end-use product; [TGA] = Technical grade of the active ingredient; [TW] = Treated wood**

15 This study is required only in support of antimicrobial uses.

16 This study is required in support of both antimicrobial and conventional uses.

17 The wipe study is based on the need to assess dermal and incidental oral exposures to children (age 1-2) playing on pressure treated decks and play sets.

18 The results of the Activated Sludge, Respiration Inhibition Test (ASRI), GLN 850.3300, will determine which of the four biodegradation tests are required.

If the ASRI test results in an EC50 of less than or equal to 20 mg/L, then either the (i) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, GLN 835.3280, (ii) the Simulation Test-Aerobic Sewage Treatment: A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 is required.

If the ASRI test results in an EC50 greater than 20 mg/L, then the registrant is required to conduct either the (i) Ready Biodegradability, GLN 835.3110, (ii) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, (iii) the Simulation Test-Aerobic Sewage Treatment: A. Activated Sludge Units, or (iv) the Porous Pot Test.

If the Ready Biodegradability Study is conducted and passes, then no further testing is required. If, however, the pesticide fails the Ready Biodegradability study, then the (i) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, (ii) the Simulation Test-Aerobic Sewage Treatment: A. Activated Sludge Units, or (iii) the Porous Pot Test is required.

19 The following data/scenarios are needed: pressure treatment, liquid pour, sapstain, brush/roller, and airless sprayer.

20 See information and guidance identified in the EPA documents, (i) USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11-14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation; (ii) 2014 Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. [https://www.epa.gov/sites/production/files/2014-06/documents/pollinator\\_risk\\_assessment\\_guidance\\_06\\_19\\_14.pdf](https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf)

21 See also OECD 214: OECD.1998b. OECD Guidelines for the Testing of Chemicals. Test Number 214, Acute Contact Toxicity Test. [http://www.oecd-ilibrary.org/environment/test-no-214-honeybees-acute-contact-toxicity-test\\_9789264070189-en](http://www.oecd-ilibrary.org/environment/test-no-214-honeybees-acute-contact-toxicity-test_9789264070189-en)

22 Product use data is needed to clarify uses (particularly the use of plastics in toys), application rates and wood retentions, and application equipment.

23 Only passerine species toxicity data are required.

24 OECD Test Guideline 209 can also be used as guidance for this study, available online at <http://www.oecd-ilibrary.org/content/book/9789264070080-en>

25 In a Federal Register Notice dated June 27, 2012, EPA split the Public Draft OPPTS 850.5400 test guideline into two test guidelines: OCSPP 850.4500 and OCSPP 850.4550. See "Final Test Guidelines; OCSPP 850 Series; Notice of Availability" 77 FR 38282, June 27, 2012. <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028>.

26 Formal guidelines for semi-field tests do not yet exist; however, information that can help guide the development of a semi-field tunnel test protocol can be found at OECD 75, see: OECD. 2007. Series on Testing and Assessment Number 75. Guidance document on the honey bee (*Apis mellifera* L.) brood test under semi-field conditions. Environmental Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. ENV/JM/MONO(2007)22. 31-Aug-2007. [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2007\)22&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)22&doclanguage=en).

27 For field-feeding studies see: Oomen et al. 1992: Oomen, P. A. A. DeRuijter and J. Van der Steen. 1992. Method for honey bee brood feeding tests with insect growth-regulating insecticides. Bul OEPP/EPPO Bulletin 22: 613-616.

28 Foliar dislodgeable and turf transferrable residue dissipation data are required for post-application worker or residential exposure.

29 EPA published draft guidance under guideline 850.6800 and has since published final guidance for this study under guideline 850.3300: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0021>.

30 EPA has a published final guideline for this study: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0036>. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.

31 EPA has a published final guideline for this study: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0034>. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.

United States Environmental Protection Agency  
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**FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS**

Case # and Name: N/A - Tebuconazole

DCI Number: GDCI-128997-1598

**Key: [Degr] = Degradate; [d-EP] = diluted End-use product; [EP] = End-use product; [MET] = Plant metabolite; [MP] = Manufacturing-use product; [PAI] = Pure Active Ingredient; [PAIRA] = Pure active ingredient radio-labelled; [RAMET] = Radio-labeled plant metabolite; [ROC] = Residue of Concern; [TEP] = Typical end-use product; [TGAI] = Technical grade of the active ingredient; [TW] = Treated wood**

- 32 EPA has a published final guideline for this study: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0024>. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.
- 33 EPA has a published final guideline for this study: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0017>. The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.
- 34 EPA has a published final guideline for this study: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0003>.
- 35 ECM/ILV needed for soil and water.
- 36 Chronic sediment toxicity data required on two freshwater species (an amphipod and a midge) in support of conventional uses. Only the freshwater amphipod data are required in support of antimicrobial uses.
- 37 Chronic sediment toxicity data required on one species of estuarine/marine amphipod.
- 38 Algal toxicity data required on two species of non-vascular plants (freshwater and marine diatoms).
- 39 A waiver may be requested for all applications if a residue screening level default at 100% of the application rate does not trigger risk concerns.
- 40 A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. The following elements could be considered when developing study protocol(s) for the monitoring of residues in pollen/nectar.
- 1) Consideration of the range of application methods and environmental conditions (e.g., soil and hydric regimes) that the target crop(s) may be under.
  - 2) Consideration of the attractiveness of the selected crop to pollinators.
  - 3) Consideration of a collection schedule sufficient to allow for an understanding of the character of residues, in the pollen/nectar and/or plant tissues, over time.
  - 4) Consideration of data sufficient to determine whether residues of the active ingredient and/or degradation product(s) accumulates in soil and is/are bioavailable for plant to uptake in a following planting, and therefore result in potential exposure to pollinators.
  - 5) Consideration of the market proportion of the selected target crop(s).
- 41 A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.

## INSTRUCTIONS: REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM

These instructions apply to the form titled "Requirements Status and Registrant's Response" and are to be used to respond to generic Data Call-Ins issued as part of EPA's Registration Review program under the Federal Insecticide, Fungicide, and Rodenticide Act.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency. You may provide additional information that does not fit on the form in a signed letter that accompanies this response. For example, you may wish to report that your product has already been transferred to another company or that the product has already been voluntarily cancelled.

The public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. N.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

Item #	DATA CALL-IN RESPONSE Information
1	This item completed by the Agency provides identifying information for the company subject to the Data Call-In.
2	This item completed by the Agency identifies the case number, case name, EPA chemical number and chemical name.
3	<p>This item completed by the Agency identifies the type of Data Call-In. The date of issuance is date stamped.</p> <p>Note the unique identification number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.</p>
4	<p>This item completed by the Agency identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies.</p> <p>Note: Required studies for which no guideline exists (i.e., "special studies), registrants are generally required to submit a protocol for EPA review prior to initiating the study.</p>

5	<p>This item completed by the Agency identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.</p> <p>If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Generic Requirements Status and Registrant's Response Forms and Instructions Form.</p>
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Item #	DATA CALL-IN RESPONSE Information
6	<p>This item completed by the Agency identifies the code associated with the use pattern of the pesticide. A brief description of each code follows:</p> <ul style="list-style-type: none"> <li>A Terrestrial food</li> <li>B Terrestrial feed</li> <li>C Terrestrial non-food</li> <li>D Aquatic food</li> <li>E Aquatic non-food outdoor</li> <li>F Aquatic non-food industrial</li> <li>G Aquatic non-food residential</li> <li>H Greenhouse food</li> <li>I Greenhouse non-food crop</li> <li>J Forestry</li> <li>K Residential</li> <li>L Indoor food</li> <li>M Indoor non-food</li> <li>N Indoor medical</li> <li>O Indoor residential</li> <li>P Aquatic non-food crop</li> <li>Q Residential outdoor</li> <li>R Agricultural premises and equipment</li> <li>S Food handling/storage establishments, premises, &amp; equipment</li> <li>T Commercial, institutional &amp; industrial premises, &amp; equipment</li> <li>U Residential and public access premises</li> <li>V Medical premises and equipment</li> <li>W Human drinking water systems</li> <li>X Materials preservatives</li> <li>Y Industrial processes and water systems – once through</li> <li>Z Industrial processes and water systems – not once through</li> <li>AA Antifouling coatings</li> <li>BB Wood preservatives</li> <li>CC Swimming pools</li> <li>DD Aquatic areas</li> <li>EE Indoor use</li> <li>FF High exposure antimicrobial</li> <li>GG Low exposure antimicrobial</li> <li>HH Occupational use conventional chemical</li> <li>II Residential use conventional chemical</li> </ul>



7	<p>This item completed by the Agency identifies the code assigned to the substance that must be used for testing. A brief description of each code follows: MP: Manufacturing-Use Product</p> <p><b>EUP:</b> End-Use Product  <b>MP:</b> Manufacturing-Use Product  <b>MP/TGAI:</b> Manufacturing-Use Product and Technical Grade Active Ingredient  <b>PAI:</b> Pure Active Ingredient  <b>PAI/M:</b> Pure Active Ingredient and Metabolites  <b>PAI/PAIRA:</b> Pure Active Ingredient or Pure Active Ingredient Radiolabeled  <b>PAIRA:</b> Pure Active Ingredient Radiolabeled  <b>PAIRA/M:</b> Pure Active Ingredient Radiolabeled and Metabolites  <b>PAIRA/PM:</b> Pure Active Ingredient Radiolabeled and Plant Metabolites  <b>TEP:</b> Typical End-Use Product  <b>TEP ____%:</b> Typical End-Use Product, Percent Active Ingredient Specified  <b>TEP/MET:</b> Typical End-Use Product and Metabolites  <b>TEP/PAI/M:</b> Typical End-Use Product or Pure Active Ingredient and Metabolites  <b>TGAI:</b> Technical Grade Active Ingredient  <b>TGAI/PAI:</b> Technical Grade Active Ingredient or Pure Active Ingredient  <b>TGAI/PAIRA:</b> Technical Grade Active Ingredient or Pure Active Ingredient Radiolabeled  <b>TGAI/TEP:</b> Technical Grade Active Ingredient or Typical End-Use Product  <b>MET:</b> Metabolites  <b>IMP:</b> Impurities  <b>DEGR:</b> Degradates</p>
8	<p>This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5. The time frame runs from the date of your receipt of the Data Call-In notice.</p>

Item #	DATA CALL-IN RESPONSE Information
9	<p>Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.</p> <ol style="list-style-type: none"> <li><b>Developing Data:</b> I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.</li> <li><b>Agreement to Cost Share:</b> I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.</li> <li><b>Offer to Cost Share:</b> I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.</li> <li><b>Submitting Existing Data:</b> I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.</li> <li><b>Upgrading a Study:</b> I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.</li> <li><b>Citing a Study:</b> I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.</li> <li><b>Deleting Uses:</b> I am attaching an application to amend my product's (or products') labeling to delete the uses for which the data are required.</li> <li><b>Low Volume/Minor Use Waiver Request:</b> I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that unless the Agency provides a written response waiving the requirement to submit data, the data remain required and are to be submitted according to the timelines specified in the Data Call-In Notice.</li> <li><b>Request for Waiver of Data:</b> I have read the statements concerning data waivers other than low volume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that unless the Agency provides a written response waiving the requirement to submit data, the data remain required and are to be submitted according to the timelines specified in the Data Call-In Notice.</li> </ol>

**Attachment 4. List of All Registrants Sent this Data  
Call-In Notice**

United States Environmental Protection Agency  
Washington, D.C. 20460

OMB Approval 2070-0174

**LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE**

Case # and Name: N/A - Tebuconazole

DCI Number: GDCI-128997-1598

Co. Nr.	Company Name	Agent For Company	Address	City	State	ZIP
69361	REPAR CORP	MANDAVA ASSOCIATES, LLC	1050 CONNECTICUT AVE, NW, SUITE 500	WASHINGTON	DC	20036
42519	LUXEMBOURG-PAMOL, INC.		12733 DIRECTOR'S LOOP	WOODBIDGE	VA	22192
74405	KOPPERS PERFORMANCE CHEMICALS NEW ZEALAND	KOPPERS PERFORMANCE CHEMICALS INC.	1016 EVEREE INN ROAD	GRIFFIN	GA	30224
82542	SOURCE DYNAMICS, LLC		12230 E. DEL NORTE	YUMA	AZ	853677355
70506	UNITED PHOSPHORUS, INC		4110 136TH ST. CT NW	GIG HARBOR	WA	98332
81598	ROTAM LIMITED	IPM RESOURCES LLC	7217 LANCASTER PIKE, SUITE A, P.O. Box 640	HOCKESSIN	DE	19707
74054	ADAMA IRVITA N.V.	MAKHTESHIM-AGAN OF NORTH AMERICA INC	3120 HIGHWOODS BLVD., SUITE 100	RALEIGH	NC	27604
34704	LOVELAND PRODUCTS, INC.		P.O. Box 1286	GREELEY	CO	806321286
75506	ARCH TREATMENT TECHNOLOGIES, INC.		360 INTERSTATE NORTH PARKWAY, SUITE 450	ATLANTA	GA	30339
39967	LANXESS CORPORATION		111 RIDC PARK WEST DRIVE	PITTSBURGH	PA	152751112
74530	HELM AGRO US, INC.	CERES INTERNATIONAL LLC	1087 HEARTSEASE DRIVE	WEST CHESTER	PA	19382
83520	TACOMA AG, LLC	BIOLOGIC, INC.	4110 136TH ST, CT NW	GIG HARBOR	WA	98332
82633	SHARDA CROPCHEM LIMITED	WAGNER REGULATORY ASSOCIATES, INC.	P.O. Box 640	HOCKESSIN	DE	19707
228	NUFARM AMERICAS, INC.		4020 AERIAL CENTER PKWY., STE. 101	MORRISVILLE	NC	27560
83997	VIANCE, LLC		8001 IBM DRIVE	CHARLOTTE	NC	28262
87427	AXSS TECHNICAL HOLDINGS, LLC	PYXIS REGULATORY CONSULTING INC	4110 136TH ST CT NW	GIG HARBOR	WA	98332
92617	KOP-COAT, INC.		3040 WILLIAM PITT WAY	PITTSBURGH	PA	15238
89168	LIBERTY CROP PROTECTION, LLC		4850 HAHNS PEAK DRIVE, SUITE 200	LOVELAND	CO	80538
3008	KOPPERS PERFORMANCE CHEMICALS, INC.		1016 EVEREE INN ROAD	GRIFFIN	GA	30224
75341	OSMOSE UTILITIES SERVICES, INC.		635 HWY. 74 S.	PEACHTREE CITY	GA	30269
75101	ARCH WOOD PROTECTION (NZ) LIMITED	ARCH WOOD PROTECTION, INC.	360 INTERSTATE N. PKWY., SUITE 450	ATLANTA	GA	30339

United States Environmental Protection Agency  
Washington, D.C. 20460

OMB Approval 2070-0174

## LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: N/A - Tebuconazole

90736	JIANGSU FENGDENG CROP SCIENCE CO., LTD.	PYXIS REGULATORY CONSULTING, INC.	4110 136TH ST., CT. NW	GIG HARBOR	WA	98332
84229	TIDE INTERNATIONAL, USA, INC.		4110 136TH ST. NW	GIG HARBOR	WA	98332
42750	ALBAUGH, LLC		P.O. Box 2127	VALDOSTA	GA	316042127
87811	WILLOWOOD TEBUCONAZOLE, LLC	PYXIS REGULATORY CONSULTING INC	4110 136TH ST., NW	GIG HARBOR	WA	98332
55146	NUFARM AMERICAS, INC.		4020 AERIAL CENTER PKWY., STE 101	MORRISVILLE	NC	27560
264	BAYER CROPSCIENCE LP		2 T.W. ALEXANDER DRIVE, P.O. Box 12014	RESEARCH TRIANGLE PARK	NC	27709
62190	ARCH WOOD PROTECTION, INC.		360 INTERSTATE NORTH PARKWAY, SUITE 450	ATLANTA	GA	30339

## **Attachment 5. Additional Documents and Information**

## **LINKS TO FORMS:**

The pesticide registration forms that are listed below can be found at:

<http://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-20-forms-and-how-obtain-them>

Link to Confidential Statement of Formula and Instructions (Form # 8570-4):

[http://www.epa.gov/sites/production/files/2013-07/documents/8570-4\\_0.pdf](http://www.epa.gov/sites/production/files/2013-07/documents/8570-4_0.pdf)

Certification of Attempt to Enter Into an Agreement With Registrants for Development of Data (Form # 8570-32):

<http://www.epa.gov/sites/production/files/2015-10/documents/8570-32.pdf>

Certification With Respect to Citation of Data (Form # 8570-34):

<http://www.epa.gov/sites/production/files/2013-08/documents/8570-34.pdf>

## **ATTENTION DCI RESPONDENTS:**

The supporting statement for the Information Collection Request (ICR) covering this DCI request is entitled

“Pesticides Data Call-In Program” (OMB No. 2070-0174; EPA No. 2288.01).

For more information about the Agency’s burden estimates, please go to the following RegInfo.gov website produced by the office of Management and Budget (OMB):

<http://www.reginfo.gov/public/do/PRAMain>.

From this site location, under the “Information Collection Review” heading, submit a search by the agency name, or, in the blue bar area at top right of the page, select “ICR” and in the search window nearby type the OMB control number (2070-0174), then click on the “Go” button at the right of the search window.

Specifically the ICR associated with the DCI request is located at:

<http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=2070-0174>.